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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,202	01/09/2001	Robert J. Miller	GC-10.6-CON	8824

24536 7590 02/07/2002

GENZYME CORPORATION  
LEGAL DEPARTMENT  
15 PLEASANT ST CONNECTOR  
FRAMINGHAM, MA 01701-9322

EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 02/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/757,202

Applicant(s)

MILLER ET AL.

Examiner

EVERETT WHITE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15-30 and 60-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-30 and 60-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-30 and 60-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,760,200. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and U.S. Pat. 5,760,200 set forth claims directed to a method of making a water insoluble biocompatible composition comprising combining in an aqueous mixture a polyanionic polysaccharide, nucleophile, and an activating agent under conditions sufficient to form said composition. Examples of the polyanionic polysaccharides, nucleophiles, and activating agents that are used in the instant application are analogous to the polyanionic polysaccharides, nucleophiles, and activating agents used in U.S. Patent No. 5,760,200. The claims of the instant application differ from the claims of U.S. Patent No. 5,760,200 by further including a modifying agent. However, U.S. Patent No.

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5,760,200 does embrace the inclusion of modifying agents in their preparation since the patent does indicate in the specification of the patent the present of modifying agents in the composition. The modifying agents set forth in the instant claims are analogous to the modifying agents disclosed in U.S. Patent No. 5,760,200. The instant application and U.S. Patent No. 5,760,200 also set forth claims directed to the compositions prepared by the claimed methods.

Claims 15-30 and 60-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,174,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and U.S. Pat. 6,174,999 set forth claims directed to a method of making a water insoluble biocompatible composition comprising combining in an aqueous mixture a polyanionic polysaccharide, nucleophile, and an activating agent under conditions sufficient to form said composition. Examples of the polyanionic polysaccharides, nucleophiles, and activating agents that are used in the instant application are analogous to the polyanionic polysaccharides, nucleophiles, and activating agents used in U.S. Patent No. 6,174,999. The claims of the instant application differ from the claims of U.S. Patent No. 6,174,999 by further including a modifying agent. However, U.S. Patent No. 6,174,999 does embrace the inclusion of modifying agents in their preparation since the patent does indicate in the specification of the patent the present of modifying agents in the composition. The modifying agents set forth in the instant claims are analogous to

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the modifying agents disclosed in U.S. Patent No. 5,760,200. The instant application and U.S. Patent No. 6,174,999 also set forth claims directed to the compositions prepared by the claimed methods.

### **State of the Art**

Hamilton et al (US Patent No. 4,937,270) and Burns et al (US Patent Nos. 5,017,229 and 5,527,893), all which disclose water insoluble derivatives of polyanionic polysaccharides, and Kuo et al (US Patent No. 6,096,727), which discloses a modified hyaluronic acid crosslinked with biscarbodiimide, have all been cited to further show the state of the art.

### **Examiner's Telephone Number, Fax Number, and Other Information**

For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. white whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or preceding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*E. White*

E. White



GARY GEIST  
SUPERVISORY PATENT EXAMINER  
TECH CENTER 1600